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Request for Continued Examination (RCE) Transmittal

Address to:
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Application Number	10/072,900
Filing Date	February 12, 2002
First Named Inventor	Arnould-Reguigne, Isabelle
Art Unit	1649
Examiner Name	Gregory S. Emch
Attorney Docket Number	116696-004

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

   a. [✓] Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

      i. [ ] Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

      ii. [ ] Other _____

   b. [✓] Enclosed

      i. [✓] Amendment/Reply

      ii. [✓] Affidavit(s)/ Declaration(s)

      iii. [ ] Information Disclosure Statement (IDS)

      iv. [ ] Other _____

2. Miscellaneous

   a. [ ] Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

   b. [ ] Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

   a. [✓] The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 02-1818. I have enclosed a duplicate copy of this sheet.

      i. [✓] RCE fee required under 37 CFR 1.17(e)

      ii. [✓] Extension of time fee (37 CFR 1.136 and 1.17)

      iii. [ ] Other _____

   b. [ ] Check in the amount of $ _____ enclosed

   c. [ ] Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature		Date	21 December 2006
Name (Print/Type)	Dean H. Nakamura	Registration No.	33,981

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Signature			
Name (Print/Type)		Date	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Arnould-Reguigne et al.
Appl. No.:	10/072,900
Conf. No.:	3572
Filed:	12 February 2002
Title:	NUCLEIC ACIDS OF THE HUMAN ABCA12 GENE, VECTORS CONTAINING SUCH NUCLEIC ACIDS AND USES THEREOF
Art Unit:	1649
Examiner:	G. Emch
Docket No.:	116696-004

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Sir:

This Amendment accompanies the Request for Continued Prosecution filed concurrently herewith requesting entry of the previously filed Amendment of 19 May 2006, and addresses issues raised in the Final Office Action mailed 21 December 2005 and the Advisory Action mailed 1 June 2006. Attached hereto and herein and incorporated by reference is a Petition for Extension of Time for a four-month extension relative to the Notice of Appeal filed 21 June 2006, making the due date for response, 21 December 2006.

Please amend the above-identified patent application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 6 of this paper.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (currently amended): An isolated nucleic acid comprising any one of SEQ ID NOs: 1-4, or a full length complement thereof, ~~encoding a polypeptide with~~ wherein said isolated nucleic acid encodes ABCA12 ~~function~~.

Claim 2 (canceled)

Claim 3 (currently amended): An isolated nucleic acid comprising a nucleic acid sequence that has at least 80% nucleotide identity with a nucleic acid comprising any one of SEQ ID NOs: 1-4, or a full length complement thereof, wherein a polypeptide encoded by said isolated nucleic acid or complement thereof binds ATP, comprises a transmembrane domain, is an ABCA member or a combination thereof~~, encoding a polypeptide with ABCA12 function~~.

Claim 4 (previously presented): The isolated nucleic acid according to claim 3, wherein the nucleic acid sequence has at least 85% nucleotide identity with the nucleic acid comprising any one of SEQ ID NOs: 1-4.

Claim 5 (currently amended): The isolated nucleic acid of claim 3, wherein said ~~An~~ isolated nucleic acid is at least 1,000 nucleotides in length ~~that~~ and hybridizes in 5X SSC at 60°C with a nucleic acid comprising any one of SEQ ID NOs: 1-4, or a full length complement thereof~~, encoding a polypeptide with ABCA12 function~~.

Claim 6 (canceled)

Claim 7 (currently amended): A nucleotide probe or primer specific for the ABCA12 gene, wherein the nucleotide probe or primer ~~comprises no more than 50~~ consists of 8, 9, 10, 12, 15, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 30, 35, 40, 45, 50, 70, 80, 100, 200 or 500 consecutive nucleotides of a nucleotide sequence of any one of SEQ ID NOs: 1-4, or a full length complement ~~thereof~~ of said probe or primer.

Claim 8 (currently amended): A nucleotide probe or primer specific for the ABCA12 gene, wherein the nucleotide probe or primer ~~comprises~~ consists of a nucleotide sequence of any one of SEQ ID NOs: 7-38, or a full length complement thereof.

Claim 9 (original): The nucleotide probe or primer according to any of claim 7 or 8, wherein the nucleotide probe or primer comprises a marker compound.

Claims 10-11 (canceled)

Claim 12 (original): A kit for amplifying the nucleic acid according to claim 1, wherein the kit comprises: a) two nucleotide primers whose hybridization position is located respectively 5' and 3' of the region of the nucleic acid; and optionally, b) reagents necessary for an amplification reaction.

Claim 13 (currently amended): The kit according to claim 12, wherein the two nucleotide primers are selected from the group consisting of a) a nucleotide primer ~~comprising no more than 50~~ consisting of 8, 9, 10, 12, 15, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 30, 35, 40, 45, 50, 70, 80, 100, 200 or 500 consecutive nucleotides of a nucleotide sequence of any one of SEQ ID NOs: 1-4, or ~~of~~ a complementary nucleotide sequence thereof, and b) a nucleotide primer ~~comprising~~ consisting of a nucleotide sequence of any one of SEQ ID NOs: 7-38, or a complementary sequence thereof.

Claims 14-15 (canceled)

Claim 16 (previously presented): A kit for detecting the nucleic acid according to claim 1, wherein the kit comprises a) a nucleotide primer as in claim 7 or a nucleotide primer as in claim 8, and optionally, b) reagents necessary for a hybridization reaction.

Claim 17 (original): The kit according to claim 16, wherein the probe is immobilized on a support.

Claim 18 (previously presented): A recombinant vector comprising the nucleic acid according to claim 1.

Claim 19 (original): The vector according to claim 18, wherein the vector is an adenovirus.

Claim 20 (original): A recombinant host cell comprising the recombinant vector according to claim 19.

Claim 21 (previously presented): An isolated recombinant host cell comprising the nucleic acid according claim 1.

Claim 22 (original): An isolated nucleic acid encoding a polypeptide comprising an amino acid sequence of any one of SEQ ID NO:5 or 6.

Claim 23 (original): A recombinant vector comprising the nucleic acid according to claim 22.

Claim 24 (previously presented): An isolated recombinant host cell comprising the nucleic acid according to claim 22.

Claim 25 (previously presented): An isolated recombinant host cell comprising the recombinant vector according to claim 23.

Claim 26-40 (canceled)

Claim 41 (previously presented): The isolated nucleic acid according to claim 3, wherein the nucleic acid sequence has at least 90% nucleotide identity with the nucleic acid comprising any one of SEQ ID NOs: 1-4.

Claim 42 (previously presented): The isolated nucleic acid according to claim 3, wherein the nucleic acid sequence has at least 95% nucleotide identity with the nucleic acid comprising any one of SEQ ID NOs: 1-4.

Claim 43 (previously presented): The isolated nucleic acid according to claim 3, wherein the nucleic acid sequence has at least 98% nucleotide identity with the nucleic acid comprising any one of SEQ ID NOs: 1-4.

Claims 44-46 (canceled)

Claim 47 (currently amended) The isolated nucleic acid according to claim 5~~2~~, wherein the nucleic acid comprises at least 1,500 consecutive nucleotides.

Claims 48-50 (canceled)

Claim 51 (previously presented): The isolated nucleic acid according to claim 5, wherein the nucleic acid comprises at least 1,500 nucleotides.

Claim 52 (currently amended): The probe or primer according to claim 7, wherein the probe or primer ~~comprises no more than 40~~ consists of 8, 9, 10, 12, 15, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 30, 35, 40 consecutive nucleotides.

Claim 53 (currently amended): The probe or primer according to claim 7, wherein the probe or primer ~~comprises no more than 35~~ consists of 8, 9, 10, 12, 15, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 30 or 35 consecutive nucleotides.

Claim 54 (currently amended): The probe or primer according to claim 7, wherein the probe or primer ~~comprises no more than 25~~ consists of 8, 9, 10, 12, 15, 18, 19, 20, 21, 22, 23, 24 or 25 consecutive nucleotides.

Claim 55 (currently amended): The probe or primer according to claim 7, wherein the probe or primer ~~comprises no more than 20~~ consists of 8, 9, 10, 12, 15, 18, 19 or 20 consecutive nucleotides.

Claim 56 (currently amended): The kit according to claim 13, wherein the primer of ~~step~~ (a) ~~comprises no more than 40~~ consists of 8, 9, 10, 12, 15, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 30, 35, 40 consecutive nucleotides.

Claim 57 (currently amended): The kit according to claim 13, wherein the primer of ~~step~~ (a) ~~comprises no more than 35~~ consists of 8, 9, 10, 12, 15, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 30 or 35 consecutive nucleotides.

Claim 58 (currently amended): The kit according to claim 13, wherein the primer of ~~step~~ (a) ~~comprises no more than 25~~ consists of 8, 9, 10, 12, 15, 18, 19, 20, 21, 22, 23, 24 or 25 consecutive nucleotides.

Claim 59 (currently amended): The kit according to claim 13, wherein the primer of ~~step~~ (a) ~~comprises no more than 20~~ consists of 8, 9, 10, 12, 15, 18, 19 or 20 consecutive nucleotides.

Claim 60 (currently amended): The kit according to claim 16, wherein the probe or primer of ~~item (1) comprises no more than 40~~ (a) consists of 8, 9, 10, 12, 15, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 30, 35, 40 consecutive nucleotides.

Claim 61 (currently amended): The kit according to claim 16, wherein the probe or primer of ~~item (1) comprises no more than 35~~ (a) consists of 8, 9, 10, 12, 15, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 30 or 35 consecutive nucleotides.

Claim 62 (currently amended): The kit according to claim 16, wherein the probe or primer of ~~item (1) comprises no more than 25~~ (a) consists of 8, 9, 10, 12, 15, 18, 19, 20, 21, 22, 23, 24 or 25 consecutive nucleotides.

Claim 63 (currently amended): The kit according to claim 16, wherein the probe or primer of ~~item (1) comprises no more than 20~~ (a) consists of 8, 9, 10, 12, 15, 18, 19 or 20 consecutive nucleotides.

REMARKS

1. Primers or probes of particular length are taught on page 11, first and second full paragraphs, on page 32, fourth full paragraph and in Table 3 of the instant specification. Hence, no issue of new matter arises and entry of the amendments is requested respectfully.

2. Claims 1-5, 7-9, 12, 13, 16-25, 41-43, 47 and 51-63 were rejected under 35 U.S.C. §§ 101 and 112, first paragraph. The Examiner believed the claims are not supported by a specific and substantial asserted utility or a well established utility and thus, also are not enabled. In the Advisory Action, the Examiner stated that while there is a link between the gene of interest and a particular disease, there was alleged to be a gap between stating that a marker is linked to a gene as compared to a marker being the particular morbid gene of a particular disorder.

The two rejections are traversed for the following reasons.

In the art of gene mapping and the practical use of discernable markers for genetic diagnosis of a disease, trait or other phenotype feature, any distinguishable marker that statistically or physically is found to be linked to a disorder, trait or other phenotype feature, can be used in a diagnostic assay to discern the presence or not of the disorder, trait or other phenotype feature. It is not necessary that the marker be the particular controlling gene of that disorder, trait or other phenotype feature. The closer the marker is to the controlling gene, the less likelihood of crossing over between the marker and the controlling gene, and the more predictable the marker will be for the presence or not of the controlling gene. Linkage analysis is a foundational feature of classical Mendelian genetics and serves as the basis for diagnostic assays to track a controlling gene, for example, when a polymorphism of the particular controlling gene is not available. A suitable maker is beneficial to track a trait, disease or other phenotype feature if the controlling gene has yet to be identified. Moreover, the chromosomal location of the trait, disease or other phenotype feature need not be known so long as the coexpression or simultaneous presence of the marker and of the trait, disease of other phenotype feature is established. The advent of DNA sequencing has provided numerous molecular

markers which has facilitated the use of nucleic acid polymorphisms as tags of a controlling gene in diagnostic assays.

The instant application relates to the discovery of a particular gene that maps to the chromosomal region previously found to be syntenic with various diseases, including ichthyosis. Because the gene is mapped to the same chromosomal region where those disorders are mapped, on its face, that leads to the conclusion that the gene is a marker for those disorders. The instant application describes polymorphisms of the ABCA12 gene that enables the artisan to identify different forms of the gene. That teaching makes clear there are discernable markers for ABCA12, and those markers can be used for ascertaining the presence of a disorder mapping to that same region or which is found, for example, to be linked to a polymorphism of ABCA12.

Attached hereto is the executed Declaration of Dr. Nicholas Duverger. As one of ordinary skill in the art, Dr. Duverger, on reading the application, concluded that based on the teachings of the specification, the instant inventors were in possession of a diagnostic assay for diseases that map to the same chromosomal region where the ABCA12 gene resides. Thus, the instant specification conveyed to one of skill in the art that the inventors described and were in possession of a diagnostic assay for diseases, such as ichthyosis, mapped to the particular chromosomal region where the ABCA12 gene was localized.

Clearly, the instant application, and hence the claims, provide a number of specific, substantial and credible uses of the nucleic acids of interest. The specification teaches thoroughly how to make and how to use a nucleic acid of interest. For example, probes identifying a mutation can be designed and used in a diagnostic assay for ichthyosis, as taught in the instant application. Therefore, utility exists and a prima facie case of non-enablement has not been made. Accordingly, withdrawal of the § 101 and § 112, first paragraph rejections is requested respectfully.

3. On page 6 of the Office Action, claims 2-5, 41-43, 47 and 51 were rejected under 35 U.S.C. § 112, first paragraph for an alleged want of written description. The Examiner maintained that the specification does not describe how to modify the nucleic acid of interest.

The rejection is traversed for the following reasons.

The claimed invention relates to nucleic acids encoding polypeptides with ABCA12 function, as clearly stated in the instant application, and some of those properties are recited in the claims.

Also, the specification teaches the association of ABCA12 with certain linked markers. Thus, any one fragment can be mapped to determine whether that nucleic acid retains the property of mapping to the chromosomal region where the genomic copy of the gene resides. Also, the instant specification teaches association of the ABCA12 gene expression with markers of skin and epithelium. Thus, the artisan can determine whether a fragment retains the association with the particular tissue expression of ABCA12.

Thus, the instant specification provides the sequences of ABCA12, characterizes the gene, the transcripts and polymorphisms thereof, and describes uses of the subject matter of interest. Hence, the written description requirement being satisfied, withdrawal of the rejection is in order.

4. On page 7 of the Office Action, claims 2, 5, 7, 9, 13, 16, 17, 47 and 51-63 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. The issue relates to new matter, and more specifically of the possible need to recite probes of particular size that are not explicitly recited in the specification.

The rejection is traversed for the following reasons.

The nucleic acids relate to expressing an ABCA12 function or identifying a nucleic acid expressing an ABCA12 function. The nucleic acids also are related to markers for particular disease and other markers that map to the same chromosomal region and have the same tissue distribution.

The specification teaches nucleotides of interest of at least 1000 bp in length, for example, or 50 bp or fewer, for example, 40 bp or fewer, 35 bp or fewer, 25 bp or fewer, and 20 bp or fewer bp, see page 11, third full paragraph. That paragraph teaches nucleotides comprising 1500 bp as well.

Further examples are provided in paragraph 1 hereinabove. Also, the instant specification teaches a variety of polypeptides.

Thus, the specification clearly teaches a number of nucleic acids that comply with and are described by the language found objectionable. It is well settled that there need not be ipsissimis verbis concordance between the language in the specification and in the claims. All that is required is that the specification reasonably convey to the artisan what is being claimed, and the instant specification, in light of the state of the art of making and using probes, clearly teaches an extensive range of usable polynucleotides.

Nevertheless, for the purpose of compact prosecution, the claims were amended to recite probes of particular size explicitly recited in the specification. Clearly, an artisan would well recognize that once a probe or primer of particular size is obtained, one or more bases can be added to or removed from the probe or primer without departing from the spirit of the claimed invention. An artisan would well be able to practice the methods taught in the instant application and as known in the art to ascertain whether any variant of a probe or primer of particular claimed length having one or more bases added to or removed from retains the desired function and properties of interest.

The rejection now can be withdrawn.

5. Beginning at page 8 of the Office Action, the Examiner rejected claim 16 under 35 U.S.C. § 112, second paragraph.

Applicants thank the Examiner, his suggestion was adopted and hence, withdrawal of the rejection is requested respectfully.

6. On page 9 of the Office Action, the Examiner rejected claims 7, 13, 16 and 52-63 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by the GenBank sequence of Ansorge et al.

The rejection is traversed for the following reasons.

The GenBank sequence of Ansorge et al. relates to a particular partial nucleic acid sequence. That GenBank sequence neither teaches nor suggests the claimed nucleic acids.

Thus, there is no anticipation and the rejection can be removed.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance. Reexamination, reconsideration, withdrawal of the rejections, and early indication of allowance are requested respectfully. Should the Examiner believe that an interview would advance the prosecution of the instant application, Applicants invite her to contact the undersigned at the local exchange noted below.

The Commissioner is authorized to credit or debit Deposit Account No. 29180 if needed as relating to this paper to maintain pendency of the instant application. Finally, the undersigned avers having authority to act on behalf of applicants and the real parties in interest.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY _____

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